

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SCIELE PHARMA, INC. <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 09-037 (RBK) (JS)
)	(CONSOLIDATED)
LUPIN LTD., <i>et al.</i> ,)	
)	
Defendants.)	REDACTED VERSION
)	

**LUPIN'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR A PROTECTIVE
ORDER CONCERNING ITS HIGHLY SENSITIVE COMMERCIAL INFORMATION
INVOLVING COMMERCIAL RELATIONSHIPS AND SETTLEMENT NEGOTIATIONS**

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TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	1
FACTUAL BACKGROUND.....	3
A. Plaintiffs Request Highly Sensitive Commercial Information that is Irrelevant and Unnecessary to the Issues in this Case	3
B. Lupin Will Be Harmed by If Its Highly Sensitive Commercial Information Is Disclosed.....	4
C. Plaintiffs’ Discovery Requests Do Not Seek Relevant or Necessary Information to the Determination of Damages	5
1. Lupin’s Highly Sensitive Documents and Information Are Irrelevant and Unnecessary to Determine the Scope of the Market or Demand for the Product.....	6
2. Lupin’s Net Price and Customer Information Are Irrelevant and Unnecessary to Calculate Lost Profits Based on Price Erosion.....	7
3. Lupin’s Other Highly Sensitive Documents and Information Are Also Irrelevant and Unnecessary to Calculate Lost Profits	7
4. Lupin’s Highly Sensitive Documents and Information Are Irrelevant and Unnecessary to Calculate a Reasonable Royalty.....	8
5. Negotiations Regarding Transfer of Lupin’s ANDA Are Irrelevant.	9
D. Procedural History	10
1. The Court Denied Shionogi’s Attempt to Obtain the Same Information During Briefing of Shionogi’s Motion for a Preliminary Injunction	10
2. Shionogi Also Attempted to Obtain Lupin’s Highly Sensitive Commercial Information From Nonparties in Tennessee and Illinois	11
ARGUMENT	11
I. THE COURT SHOULD ENTER A PROTECTIVE ORDER PRECLUDING DISCOVERY OF LUPIN’S HIGHLY SENSITIVE COMMERCIAL INFORMATION BECAUSE THE DISCLOSURE OF THE INFORMATION WOULD BE EXTREMELY HARMFUL TO LUPIN.....	11

A.	As the Court Previously Held, Plaintiffs’ Discovery Requests Seek Lupin’s Highly Sensitive Commercial Information	12
B.	As the Court Previously Held, Disclosure of Lupin’s Highly Sensitive Commercial Information Would Be “Incredibly Harmful”	13
C.	Plaintiffs Cannot Establish that the Requested Information Is Relevant and Necessary to Calculate Alleged Damages	14
1.	Plaintiffs Seek Information Irrelevant and Unnecessary to Calculate Damages Based on Alleged Lost Profits	14
2.	Plaintiffs Seek Information Irrelevant and Unnecessary to Calculate Alleged Damages Based on a Reasonable Royalty	16
D.	Lupin’s Documents Concerning Negotiations or Discussions with Sandoz Are Also Irrelevant and Unnecessary to a Calculation of Alleged Damages	16
II.	THE EXISTING PROTECTIVE ORDER IS NOT SUFFICIENT TO PROTECT THE HIGHLY SENSITIVE COMMERCIAL INFORMATION REQUESTED BY SHIONOGI.....	17
	CONCLUSION.....	19

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Air Prods. & Chem., Inc. v. Inter-Chemical Ltd.</i> , No 03-6140, 2003 WL 22917491 (E.D. Pa. Dec. 2, 2003).....	13
<i>Allen v. Howmedica Leibinger, GmhH</i> , 190 F.R.D. 518 (W.D. Tenn. 1999)	13
<i>Am. Standard. Inc. v. Pfizer Inc.</i> , 828 F.2d 734 (Fed Cir. 1987).....	12
<i>Autotech Techs. Ltd. P’ship v. Automationdirect.com, Inc.</i> , 237 F.R.D. 405 (N.D. Ill. 2006).....	18
<i>Bimbo Bakeries USA, Inc. v. Botticella</i> , No. 10–0194, 2010 WL 571774 (E.D. Pa. Feb. 9, 2010)	13
<i>Duracell Inc. v. SW Consultants, Inc.</i> , 126 F.R.D. 576 (N.D. Ga. 1989).....	13
<i>Fadalla v. Life Auto. Prods., Inc.</i> , 258 F.R.D. 501 (M.D. Fla. 2007).....	13
<i>Feldman v. Cmty. Coll. of Allegheny</i> , 85 F. App’x 821 (3d Cir. 2004)	13
<i>Fleming Sales Co. v. Bailey</i> , 611 F. Supp. 507 (N.D. Ill. 1985)	18
<i>Greater Rockford Energy & Tech. Corp. v. Shell Oil Co.</i> , 138 F.R.D. 530 (C.D. Ill. 1991)	18
<i>Interactive Pictures Corp. v. Infinite Pictures, Inc.</i> , 274 F.3d 1371 (Fed. Cir. 2001).....	16
<i>Litton Indus., Inc. v. Chesapeake & Ohio Ry. Co.</i> , 128 F.R.D. 528 (E.D. Wisc. 1990).....	18
<i>Mannington Mills Inc. v. Armstrong World Indus., Inc.</i> , 206 F.R.D. 525 (D. Del. 2002)	11, 12, 13
<i>Med. Billing Consultants Inc. v. Intelligent Med. Objects</i> , No. 01 C 9148, 2003 WL 1809465 (N.D. Ill. Apr. 4, 2003).....	17

<i>Micro Motion Inc. v. Kane Steel Co.</i> , 894 F.2d 1318 (Fed. Cir. 1990).....	14, 15
<i>PepsiCo, Inc. v. Redmond</i> , 54 F.3d 1262 (7th Cir. 1995)	12
<i>Pfizer Inc. v. Apotex Inc.</i> , 731 F. Supp. 2d 754 (N.D. Ill. 2010)	17
<i>Proudfood Consulting Co. v. Gordon</i> , 576 F.3d 1223 (10th Cir. 2009)	13
<i>RyCon Specialty Foods, Inc. v. Wellshire Farms, Inc.</i> , 2011 WL 1342998 (M.D. Pa. Apr. 7, 2011).....	12
<i>Stanley Works v. Newell Co.</i> , No. 92 C 20157, 1992 WL 229652 (N.D. Ill. Aug 27, 1992).....	13
<i>State Indus., Inc. v. Mor-Flo Indus., Inc.</i> , 883 F.2d 1573 (Fed. Cir. 1989).....	16
<i>Whelan v. A. Ward. Enterprises, Inc.</i> , No. Civ. A. 01-2874, 2002 WL 1745614 (E.D. Pa. Jul. 23, 2002).....	14
<i>Wyeth v. Organus Pharma Inc.</i> , Civil Action No. 09-3235, 2010 WL 4117157 (D.N.J. Oct. 19, 2010)	17
OTHER AUTHORITIES	
Fed. R. Civ. P. 26(c)	1
Fed. R. Evid. 408	17
Rule 26(c) of the Federal Rules of Civil Procedure.....	11

INTRODUCTION

Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively “Lupin”) hereby move, pursuant to Fed. R. Civ. P. 26(c), for a protective order to preclude plaintiffs from obtaining discovery of its highly sensitive commercial information involving commercial relationships and settlement negotiations in connection with purported damages discovery. The magnitude of this question is heightened in this case because the other parties are Lupin’s direct competitors in the metformin hydrochloride extended release product market and with respect to numerous other drugs. Plaintiff Sciele Pharma, Inc., n/k/a Shionogi, Inc. (“Shionogi”) sells the branded product, Fortamet[®]. Plaintiffs Andrx Corporation, Andrx Pharmaceuticals, Inc. (n/k/a Watson Laboratories, Inc.-Florida), Andrx Pharmaceuticals, L.L.C., Andrx Pharmaceuticals, (NJ), Inc., Andrx EU, Ltd., and Andrx Labs, L.L.C. (collectively “Andrx”) are presently selling the authorized generic product. Mylan Pharmaceuticals Inc. (“Mylan”) filed an Abbreviated New Drug Application (“ANDA”) for a generic metformin hydrochloride extended release product. Moreover, Andrx, Mylan and Lupin are all generic companies that vigorously compete with each other for sales on numerous other generic products.

Due to the fierce price competition in the generic market, generic companies enter into highly confidential agreements on a customer-by-customer basis, which include special pricing and discount arrangements. If Lupin’s pricing, sales, and marketing strategies were disclosed, competitor generic companies would be able to target its customers and undercut pricing arrangements, thereby threatening Lupin’s ability to compete in the generic market for all products now and in the future.

This is not plaintiffs’ first attempt to obtain Lupin’s highly sensitive commercial information. During a hearing on October 20, 2011, in the context of the motion for the preliminary injunction, the Court previously denied Shionogi’s requests. Judge Kugler found

that the information sought by Shionogi was “particularly sensitive,” (Brauerman Decl.¹, Ex. 1 at 10:11-13), and held that Lupin need not produce the information because it would be “incredibly harmful” if disclosed to Lupin’s competitors and was not “terribly important” to Shionogi. (*Id.* at 18:1-5.)

Plaintiffs have not asserted that the nature of the information has become less sensitive or that the harm Lupin would suffer if the information were disclosed has diminished. Instead, plaintiffs claim that circumstances have changed because they are now seeking damages and they need the information to calculate damages. Shionogi relies upon a declaration from its purported damages expert, Christopher P. Gerardi, which was submitted to the Court on April 2, 2012. (Brauerman Decl., Ex. 2 at 104-23 (“Gerardi Decl.”).) Plaintiffs have failed to establish a need for Lupin’s highly sensitive information; nor have they demonstrated the relevance of the information. As detailed in the accompanying declaration by Lupin’s expert, Ivan T. Hofmann, Mr. Gerardi’s arguments are fatally flawed because they fail to take into account the unique features of a damages analysis in a patent-infringement case involving a generic drug product that allegedly infringes a branded product. According to Mr. Hofmann, who has significantly more experience than Mr. Gerardi in damages analyses involving pharmaceutical products, the highly sensitive information to which Lupin objects to producing, is neither necessary nor relevant to Shionogi’s damages calculations.

[REDACTED]

[REDACTED]

[REDACTED] Moreover, these

¹ “Brauerman Decl.” refers to the April 23, 2012 Declaration of Stephen Brauerman, Esquire, submitted in support of this motion.

negotiations have no conceivable relevance to a calculation of Shionogi's alleged lost profits or a royalty.

Accordingly, since plaintiffs have failed to establish that the information sought is relevant and necessary, plaintiffs cannot carry their burden to overcome the protection afforded to Lupin's highly sensitive information and are precluded from obtaining the requested discovery.

FACTUAL BACKGROUND

A. PLAINTIFFS REQUEST HIGHLY SENSITIVE COMMERCIAL INFORMATION THAT IS IRRELEVANT AND UNNECESSARY TO THE ISSUES IN THIS CASE

Plaintiffs have served document requests, interrogatories, a 30(b)(6) notice, and subpoenas on nonparties for the following categories of Lupin's highly sensitive commercial information that would cause Lupin to be disadvantaged commercially if disclosed: (1) the pricing of Lupin's generic metformin hydrochloride extended release product ("Lupin's ANDA Product"); (2) the identity of Lupin's customers and those customers' purchasing decisions; (3) the terms of Lupin's contracts with its customers; (4) the details of Lupin's sales to specific customers and sales channels; (5) profitability of Lupin's ANDA Product; and (6) Lupin's marketing strategy. (*See* Pl.'s Doc. Req. Nos. 33, 34, 35, 36, 37, 40, 41, 42, 43, 44, 45, 53, 79; Pl.'s Notice of 30(b)(6) Dep. Nos. 8, 13, 14, 15, 19, 22, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37 38; Pl.'s Interrogs. Nos. 1-2; Pl.'s Doc. Subpoena Req. Nos. 1-7; *see also* Brauerman Decl., Ex. 2 at 18-35, 43-62, 64-70.) Lupin objects to the production of this highly sensitive information because, in addition to being unnecessary and irrelevant to plaintiffs' damages calculations, if this information were disclosed to Lupin's competitors, it would cause Lupin

significant harm. (Brauerman Decl., Ex. 3 (“Hoffman Decl.”) at ¶ 4; Hofmann Decl.² at ¶¶ 28-30, 32-35, 40.)

B. LUPIN WILL BE HARMED BY IF ITS HIGHLY SENSITIVE COMMERCIAL INFORMATION IS DISCLOSED

Plaintiffs’ discovery requests seek highly sensitive commercial information that would cause Lupin to be “greatly disadvantaged if its competitors,” such as Shionogi, Andrx and Mylan, obtained this information. (Hoffman Decl. at ¶ 4; Hofmann Decl. at ¶ 6.) The Court acknowledged, and Shionogi conceded, the sensitive nature of the information sought during the hearing on October 20, 2011 when Shionogi attempted to obtain the information in the context of the motion for a preliminary injunction, (*see* Brauerman Decl., Ex. 1 at 10:11-14). Indeed, the harm to Lupin would not be limited to its sale of its ANDA Product. (Hoffman Decl. at ¶¶ 7-11.)

As explained further below, and as Lupin’s expert, Ivan T. Hofmann, CPA/CFF, CLP states:

The dynamic of competition among branded and generic companies and the competition among generic companies results in heightened commercial sensitivity of highly confidential information. The complexity and sensitivity is pronounced in this litigation given that one of the Plaintiffs (Watson) has recently launched a competitive authorized generic metformin hydrochloride extended release and one of the co-defendants (Mylan) may launch an additional generic metformin hydrochloride extended release product in July. [Shionogi] inappropriately requests voluminous production of highly sensitive and confidential information that is unnecessary to determine damages and would cause risk of serious harm if the documents and information are unnecessarily produced.

(Hofmann Decl. at ¶ 6.)

The net price Lupin offers its customers “is highly sensitive and if disclosed to the market [would] allow potential competitors the ability to undercut” Lupin. (Hoffman Decl. at ¶ 8.) The release of pricing information coupled with disclosure or discovery of the identity of Lupin’s

² “Hofmann Decl.” refers to the April 23, 2012 Declaration of Ivan T. Hofmann, CPA/CFF, CLP, submitted with this motion.

customers would be especially harmful as it would enable competitors to specifically target Lupin's existing customers, armed with the knowledge of what price they must beat. (*Id.*)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

The details of Lupin's sales to specific customers is "highly sensitive" and its release would have a "significant negative impact" on Lupin's current and future business. (*Id.* at ¶ 10.) Competitors could target prospective customers with this knowledge, which would compromise Lupin's ability to compete. (*Id.*)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

C. PLAINTIFFS' DISCOVERY REQUESTS DO NOT SEEK RELEVANT OR NECESSARY INFORMATION TO THE DETERMINATION OF DAMAGES

As Lupin's expert, Mr. Hofmann, finds: plaintiffs' discovery requests "are excessive, overbroad and unnecessary to calculate the alleged damages[.]" (Hofmann Decl. at ¶ 7.) Mr. Hofmann bases his opinion on his extensive experience in the calculation of damages in patent infringement cases in the pharmaceutical industry, including more than 75 projects. (Hofmann Decl. at ¶ 2.) Shionogi relies on a Declaration from its purported expert, Christopher P. Gerardi,

but Mr. Gerardi's lack of experience in patent-infringement cases in the pharmaceutical industry is demonstrated by his erroneous conclusions. (Hofmann Decl. at ¶¶ 15-16.) Mr. Gerardi's opinions are fatally flawed because they fail to consider the important characteristics of the pharmaceutical industry. (*See generally*, Hofmann Decl.)

1. Lupin's Highly Sensitive Documents and Information Are Irrelevant and Unnecessary to Determine the Scope of the Market or Demand for the Product

Unlike other patent infringement cases, a determination of alleged damages in a Hatch-Waxman case like this one does not depend upon consumers' purchasing decisions to buy either the patented product or the allegedly infringing product. (Hofmann Decl. at ¶¶ 8-9.) Rather, demand for the product is driven by physicians' prescribing behavior. (*Id.* at ¶ 10.) The branded reference produce is substituted by the generic product due to, *inter alia*, state laws that require or encourage substitution of generic products for branded products, along with other financial incentives for pharmacies to purchase (or patients to make co-payments for) generic drugs. (*Id.* at ¶ 10.) In other words, documents concerning customers' purchasing behaviors are irrelevant to alleged damages in a Hatch-Waxman case because they are not motivated by a comparison of Lupin's product to the branded product with respect to the allegedly infringed characteristics of the product. (*Id.* at ¶¶ 10, 32.)

"The availability of generics can sometimes expand the market beyond the volume of sales the branded company would have made (i.e. if prescribing physicians begin to increase prescriptions of branded and/or generic compound due to the availability of a generic)." (*Id.* at ¶ 11.) But, Lupin's highly sensitive information concerning actual sales to its customers and the terms of its business arrangements are not needed for this analysis. (*Id.* at ¶¶ 11-12.) "This potential market expansion can be analyzed using information from IMS Health, Inc. and/or based on forecasts." (*Id.* at ¶ 11.)

2. Lupin's Net Price and Customer Information Are Irrelevant and Unnecessary to Calculate Lost Profits Based on Price Erosion

As Mr. Hofmann finds: “Lost profits (if available) are calculated based on the profits of the patent holder, not the alleged infringer...Information regarding the patent holder’s profitability would come from the patent holder, not the alleged infringer.” (*Id.* at ¶ 13.) “It is unnecessary to require the alleged infringer in a generic pharmaceutical patent infringement case to produce detailed, customer specific information regarding unit sales, pricing, discounts and rebates.” (*Id.* at ¶ 14.)

Plaintiffs and Mr. Gerardi claim that Lupin’s highly sensitive, commercial information is needed to quantify lost profits from price erosion. (*See* Gerardi Decl. at ¶ 14.) But, as Mr. Hofmann states, “[p]rice erosion damages are only potentially available if a branded company shows that price erosion has actually occurred.” (Hofmann Decl. at ¶ 17.) Plaintiffs have presented no evidence that price erosion has occurred, and branded companies typically raise – not lower – prices in response to generic competition. (*Id.* at ¶¶ 18-19.) Even if price erosion has occurred, Lupin’s documents concerning its net prices to its customers “would be unnecessary to quantify a potential price erosion claim” by Shionogi. (*Id.* at ¶ 20.) Mr. Gerardi’s “suggestion that customer specific information is needed to calculate alleged price erosion reflects a lack of understanding and/or consideration of the market for prescription pharmaceuticals and the determination of price erosion damages for branded companies with generic competition.” (*Id.*)

3. Lupin's Other Highly Sensitive Documents and Information Are Also Irrelevant and Unnecessary to Calculate Lost Profits

Relying on Mr. Gerardi’s Declaration, Shionogi also claims that “Lupin’s ANDA Metformin Products sales channels and relationships with customers” and “reasons why customers purchased Lupin’s ANDA Metformin Products” are relevant to a damages analysis. (Gerardi Decl. at ¶ 11.) As Mr. Hofmann explains, however, the alleged “need for ‘customer’

information in the Gerardi Declaration, including the need for information regarding ‘the reasons why customers purchased Lupin’s ANDA Metformin Products,’ reflects the lack of either consideration or experience with the market for prescription pharmaceutical products.”

(Hofmann Decl. at ¶ 23.) The drug products reach the end users, *i.e.*, the patients, through different distribution networks, which vary from company to company, and differ based on whether the drug is branded or generic. (*Id.* at ¶¶ 23-26.) Moreover, as explained above, due to mandatory substitution laws and other financial incentives, patients may have no control over whether they receive the brand or the generic drug from a particular generic drug manufacturer.

Plaintiffs also seek “market analyses or market share analyses identifying the competitors of the accused products and competitor sales.” (Gerardi Decl. at ¶ 14.) This request “inappropriately applies concepts for patent infringement litigation in general without considering the market for Fortamet[®] and the distinct issues for pharmaceutical patent infringement litigation.” (Hofmann Decl. at ¶ 33.) A prescription written for Fortamet[®] can only be filled with Fortamet[®] or a generic drug approved by the FDA, such as Andrx’s authorized generic or Lupin’s ANDA product. (*Id.* at ¶ 34.)

Plaintiffs’ request for information concerning Lupin’s marketing, developing, manufacturing, and distribution of its ANDA products should also be denied. As set forth in the Hofmann Declaration, generic companies have different business models than brand companies, making this information irrelevant and unnecessary for a damages analysis. (*Id.* at ¶ 35.)

4. Lupin’s Highly Sensitive Documents and Information Are Irrelevant and Unnecessary to Calculate a Reasonable Royalty

Lupin’s “sales, profitability, marketing, licensing, development, manufacturing, and distribution information” are likewise irrelevant and unnecessary to the calculation of a reasonable royalty. (*Id.* at ¶ 36.) Information relating to “profitability” of the alleged infringing

product is not relevant in cases like this one. (*Id.* at ¶ 38.) Such information would only be relevant where a portion of profits is attributable to a particular feature of the patented product. (*Id.*) In this case, the entire product is assumed to infringe the patents-in-suit. (*Id.*)

“Profitability” might also be considered “to analyze the alleged infringer’s ability to pay a royalty and maintain a reasonable profit.” (*Id.* at ¶ 39.) [REDACTED]

[REDACTED]

[REDACTED]

Plaintiffs’ requests for other documents and information are equally meritless, and plaintiffs have not alleged any basis for why such documents would be needed to calculate a reasonable royalty.

5. Negotiations Regarding Transfer of Lupin’s ANDA Are Irrelevant.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

D. PROCEDURAL HISTORY

1. The Court Denied Shionogi's Attempt to Obtain the Same Information During Briefing of Shionogi's Motion for a Preliminary Injunction

In October 2011, during briefing on Shionogi's motion for a preliminary injunction, Shionogi sought the same highly sensitive commercial information from Lupin. (Brauerman Decl., Ex. 4 at 7-8.) As it does here, Lupin objected to the production of documents and information concerning its pricing, sales, volume, rebate and discount data, marketing plans, shipment information, customer names and customer contacts, because this information is highly sensitive and its disclosure – inadvertent or otherwise – would cause Lupin long-term competitive harm, and such information was not necessary to demonstrate harm to Shionogi. (Brauerman Decl., Ex. 5 at 5; Hoffman Decl. at ¶¶ 7-11.) This Court found that the pricing information sought by Shionogi was “particularly sensitive,” (Brauerman Decl., Ex 1 at 10:11-13), and questioned the relevance of the information to the issues presented by the preliminary injunction motion. (*Id.* at 11:12-14, 11:21-23, 17:20-18:3.) The Court held that Lupin's highly sensitive information did not need to be produced because it would be “incredibly harmful” if known by Lupin's competitors and was not “terribly important” to Shionogi. (Brauerman Decl., Ex 1 at 18:1-5.) Given the extreme sensitivity of the information sought, Judge Kugler also found the existence of a protective order was not sufficient protection to compel production. (*Id.* at 18:3-8.)

2. Shionogi Also Attempted to Obtain Lupin's Highly Sensitive Commercial Information From Nonparties in Tennessee and Illinois

Before the current motion schedule was set by the Court on April 5, 2012, Shionogi made no effort to ask this Court to revisit or modify its ruling. Instead, Shionogi pursued the same information from nonparties DDN and Steven Schommer in the Western District of Tennessee and in the Northern District of Illinois through subpoenas for the production of documents and testimony. DDN is a logistics provider used by Lupin during the launch of its ANDA products in September 2011, and Steven Schommer is a former DDN employee.

After Shionogi served DDN and Schommer with subpoenas, counsel for Lupin and Shionogi conducted a meet and confer during which Shionogi was unwilling to modify its position or pursue its existing discovery requests against Lupin instead of pursuing third parties. Only after Lupin incurred the time and expense of filing motions to quash the subpoenas pending in both foreign districts which, among other arguments, pointed out that a modification of Judge Kugler's order should be argued in this Court, was Shionogi willing first to resolve the discoverability of the documents in this Court. Both motions to quash are now stayed pending this Court's determination. Shionogi conceded during the April 5, 2012 status conference that this motion for a protective order would be determinative as to the subpoenas served on the nonparties. (Braerman Decl., Ex. 6 at 19:4-7.)

ARGUMENT

I. THE COURT SHOULD ENTER A PROTECTIVE ORDER PRECLUDING DISCOVERY OF LUPIN'S HIGHLY SENSITIVE COMMERCIAL INFORMATION BECAUSE THE DISCLOSURE OF THE INFORMATION WOULD BE EXTREMELY HARMFUL TO LUPIN

Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, the Court should enter a protective order providing that Lupin need not disclose its highly sensitive commercial information in response to discovery requests or during a 30(b)(6) deposition. *See Mannington*

Mills Inc. v. Armstrong World Indus., Inc., 206 F.R.D. 525, 528-29 (D. Del. 2002). When, as here, the “information sought is highly sensitive, and its disclosure harmful,” the burden shifts to plaintiffs to establish that Lupin’s “disclosure of trade secrets and highly sensitive, information is relevant and necessary to its case.” *Id.* at 528 (internal quotations removed); *see also RyCon Specialty Foods, Inc. v. Wellshire Farms, Inc.*, 2011 WL 1342998, *7 (M.D. Pa. Apr. 7, 2011); *Am. Standard. Inc. v. Pfizer Inc.*, 828 F.2d 734, 739 (Fed Cir. 1987).

A. AS THE COURT PREVIOUSLY HELD, PLAINTIFFS’ DISCOVERY REQUESTS SEEK LUPIN’S HIGHLY SENSITIVE COMMERCIAL INFORMATION

Plaintiffs seek information concerning Lupin’s: (1) pricing; (2) customers; (3) contracts; (4) sales transactions; (5) profitability; and (6) marketing strategy. (*See Factual Background*, at 3, *supra.*) This Court has already held that such information is “particularly sensitive” during discovery in connection with the motion for a preliminary injunction. (Brauerman Decl., Ex. 1. at 10:11-13.) Lupin’s Vice President of Sales and Marketing, Robert Hoffman, confirms the highly sensitive nature of this information and that Lupin has taken precautions to prevent the disclosure of such information. (*See Factual Background*, at 4-5, *supra.*) Given the highly sensitive nature of the information sought by Shionogi, Lupin takes measures to protect itself, including the use of confidentiality agreements with customers and internal processes to restrict access to this information. (Hoffman Decl. at ¶ 8.) Lupin’s expert, Ivan T. Hofmann also confirms that this type of information is considered highly sensitive to a generic company like Lupin. (*See Factual Background*, at 3-5, *supra.*) Finally, Shionogi admitted, as it must, that the information sought is highly sensitive. (*See Brauerman Decl.*, Ex. 1 at 10:11-14; *Factual Background*, at 4, *supra.*)

The foregoing is consistent with well-established principles pronounced by numerous courts. Highly sensitive commercial information in competitive markets includes “highly

confidential, financial and sales information, marketing plans, marketing reports, advertising information and expenditures, as well as other types of internal memoranda and reports.”

Mannington Mills, Inc., 206 F.R.D. at 530. *See also PepsiCo, Inc. v. Redmond*, 54 F.3d 1262, 1270 (7th Cir. 1995) (holding that “knowing exactly how [a competitor] will price, distribute, and market” its product” is a trade secret); *Stanley Works v. Newell Co.*, No. 92 C 20157, 1992 WL 229652 at *3-4 (N.D. Ill. Aug 27, 1992) (competitive information is highly sensitive); *Bimbo Bakeries USA, Inc. v. Botticella*, No. 10-0194, 2010 WL 571774, at *4, 5 (E.D. Pa. Feb. 9, 2010) (pricing information is protected commercial information); *Air Prods. & Chem., Inc. v. Inter-Chemical Ltd.*, No 03-6140, 2003 WL 22917491, at *10 (E.D. Pa. Dec. 2, 2003) (terms of contracts, amounts and timing of shipments is protected); *Proudfood Consulting Co. v. Gordon*, 576 F.3d 1223, 1233-34 (10th Cir. 2009) (lists of key contacts, pricing information, and customer information are highly sensitive); *Feldman v. Cmty. Coll. of Allegheny*, 85 F. App’x 821, 827 (3d Cir. 2004) (customer lists and customer information are highly sensitive); *Fadalla v. Life Auto. Prods., Inc.*, 258 F.R.D. 501, 506 (M.D. Fla. 2007).

B. AS THE COURT PREVIOUSLY HELD, DISCLOSURE OF LUPIN’S HIGHLY SENSITIVE COMMERCIAL INFORMATION WOULD BE “INCREDIBLY HARMFUL”

This Court previously held that the information sought by plaintiffs would be “incredibly harmful” if it fell into the hands of Lupin’s competitors. (Brauerman Decl., Ex 1 at 18:1-5; *see also* Factual Background, at 3-5, *supra*.)

Indeed, disclosure of highly sensitive, commercial information to a competitor is presumed to be more injurious than disclosure to a non-competitor. *Mannington Mills*, 206 F.R.D. at 530-31. Such disclosure is “often extremely harmful” to the party seeking to prevent discovery. *Allen v. Howmedica Leibinger, GmH*, 190 F.R.D. 518, 526 (W.D. Tenn. 1999). Disclosure of Lupin’s “strategies and tendencies which [a competitor] may use to compete with”

Lupin, (Hoffman Decl. at ¶ 11), would place the company “at a serious competitive disadvantage.” *Duracell Inc. v. SW Consultants, Inc.*, 126 F.R.D. 576, 579 (N.D. Ga. 1989). In addition, “[i]t would be divorced from reality to believe that [Shionogi] would serve as the champion of its competitor [(i.e., Lupin)] . . . to limit public disclosure” of the highly sensitive, commercial information. *Micro Motion Inc. v. Kane Steel Co.*, 894 F.2d 1318, 1325 (Fed. Cir. 1990).

C. PLAINTIFFS CANNOT ESTABLISH THAT THE REQUESTED INFORMATION IS RELEVANT AND NECESSARY TO CALCULATE ALLEGED DAMAGES

1. Plaintiffs Seek Information Irrelevant and Unnecessary to Calculate Damages Based on Alleged Lost Profits

Shionogi would be able to compute damages for alleged lost profits based on its own profitability information, information concerning the number of units of the product sold, and consideration of any market expansion resulting from entry of generic products, and deductions for royalty payments paid by Andrx to Shionogi in connection with its sale of its authorized generic. (See Hofmann Decl. at ¶¶ 10-13.) See, e.g., *Whelan v. A. Ward Enterprises, Inc.*, No. Civ. A. 01-2874, 2002 WL 1745614, at *2-3 (E.D. Pa. Jul. 23, 2002). The lost profit calculation is made more complicated by Andrx’s launch of its generic metformin hydrochloride extended release product, since two generic products are competing with Fortamet[®]. Assuming the liability issue is resolved in favor of plaintiffs, this development will require consideration of sales of Andrx’s authorized generic product. This added complexity supports Lupin’s argument in its motion to bifurcate and stay damages discovery that the Court should decide liability issues before permitting damages discovery. (See Lupin’s Motion to Bifurcate Liability and Damages and to Stay Damages Discovery.)

Plaintiffs seek a vast amount of Lupin’s highly sensitive commercial information

unnecessary and irrelevant to the foregoing calculations. Shionogi relies upon its purported expert, Mr. Gerardi. But, Mr. Gerardi's opinions are flawed because they fail to take into account the characteristics of the pharmaceutical industry that distinguish a damages calculation in a Hatch-Waxman case like this one from other types of patent infringement cases. (Hofmann Decl. at ¶¶ 7-27, 31-38.) As set forth in the Hofmann Declaration, information concerning Lupin's highly sensitive information are irrelevant and unnecessary to a damages calculation. (Hofmann Decl. at ¶¶ 28-30; Factual Background, at 5-9, *supra*.) Production of such information, by contrast, comes with the risk of disclosure to Lupin's competitors, which can cause significant harm to Lupin's ability to compete now and in the future for the ANDA Product and all other products.

That Shionogi is seeking discovery to prove lost profits does not eliminate the boundaries of permissible discovery. *See Micro Motion, Inc. v. Kane Steel Co.*, 894 F.2d 1318, 1322 (Fed. Cir. 2000). For example, in *Micro Motion, Inc. v. Kane Steel Co.*, the patentee, sought competitors' sales figures, customer names, invoices, and other information similar to the discovery sought by Shionogi. *Micro Motion*, 894 F.2d at 1321-22. The Federal Circuit rejected Micro Motion's attempt to discover such highly sensitive information as a "fishing expedition[.]" *Micro Motion*, 894 F.2d at 1327-28. As the Federal Circuit held:

[Plaintiff's] asserted entitlement to discovery of information concerning each competitor's business simply because it may seek to prove lost profit damages. If this position were correct, a patentee could, in virtually every infringement suit, immediately obtain discovery from all possible competitors by merely filing a complaint asking for damages against one. [T]he possibility for such abuse of discovery is readily apparent.

In any event, [plaintiff's] assertion of a claim for damages or even lost profit damages in itself does not provide a mantle of relevancy with respect to all of the information sought from [its competitor.] The doors of the discovery process may not be so easily opened.

Micro Motion, 894 F.2d at 1324-25.

Likewise, Shionogi's claim for damages does not entitle it to unlimited information from its competitor – Lupin.

2. Plaintiffs Seek Information Irrelevant and Unnecessary to Calculate Alleged Damages Based on a Reasonable Royalty

The primary inquiry in determining a reasonable royalty is to assess what the parties would have agreed upon at the moment before the alleged infringement commenced. *Interactive Pictures Corp. v. Infinite Pictures, Inc.*, 274 F.3d 1371, 1384-85 (Fed. Cir. 2001). The reasonable royalty analysis is comprised of two parts: determination of the royalty rate and the royalty base against which the rate is multiplied. The royalty rate is not based on the alleged infringer's actual profits or profit margin. *See State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1580 (Fed. Cir. 1989).

Plaintiffs and Mr. Gerardi have provided no basis for why Lupin's actual profit information, or other highly sensitive information concerning Lupin's actual pricing, sales, and marketing strategies, and customer information, are needed to determine a royalty rate. (Hofmann Decl. at ¶¶ 30, 37-40.) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

D. LUPIN'S DOCUMENTS CONCERNING NEGOTIATIONS OR DISCUSSIONS WITH [REDACTED] ARE ALSO IRRELEVANT AND UNNECESSARY TO A CALCULATION OF ALLEGED DAMAGES

This Court should deny Shionogi's request for "[a]ll documents and things concerning Lupin's negotiations or discussions with [REDACTED] regarding Lupin's ANDA Metformin Products."

(Brauerman Decl., Ex. 2 at 7-8, 52). This request seeks information that is irrelevant to

Shionogi's damages claims and any other issue in this case. (Hofmann Decl. at ¶ 37 n.35.) [REDACTED]

[REDACTED] As Mr. Hofmann states: "The negotiations between two generic companies for the rights to an ANDA are very different than the hypothetical negotiation for the rights to the patents in suit." (*Id.*) Indeed, documents concerning negotiations of the transaction sought by Shionogi are not comparable to documents concerning licensing agreements or the sale of a patent. Shionogi has not, and cannot, allege any basis for how these negotiations could be relevant.

Moreover, based on the foregoing, Shionogi is not permitted to seek these documents for the purported basis of calculating damages. *See Pfizer Inc. v. Apotex Inc.*, 731 F. Supp. 2d 754, 763-764 (N.D. Ill. 2010); Fed. R. Evid. 408. In relying on *Wyeth v. Organon Pharma Inc.*, Civil Action No. 09-3235, 2010 WL 4117157 (D.N.J. Oct. 19, 2010), Shionogi fails to appreciate the distinction between the settlement negotiations and discussions on one hand and the final settlement agreements on the other. (Brauerman Decl., Ex. 2 at 7-8.) The former are not discoverable, especially whereas here they are entirely irrelevant to any issue in the case and have no bearing on a computation of damages. *Pfizer*, 731 F. Supp. 2d at 763-64.

II. THE EXISTING PROTECTIVE ORDER IS NOT SUFFICIENT TO PROTECT THE HIGHLY SENSITIVE COMMERCIAL INFORMATION REQUESTED BY SHIONOGI

Although there is a stipulated protective order in this litigation concerning documents produced to other parties, it is not sufficient to address the concerns Lupin presents in this motion. (Brauerman Decl., Exs. 7 at 1-20, 1 at 18:1-5; Hofmann Decl. at ¶ 28.) As this Court

and others have recognized, there are still risks associated with producing highly sensitive commercial information even with a protective order. “While a protective order may ensure the secrecy of the disclosed information, it will not alleviate all concerns related to the disclosure of the evidence.” *Med. Billing Consultants Inc. v. Intelligent Med. Objects*, No. 01 C 9148, 2003 WL 1809465, at *2 (N.D. Ill. Apr. 4, 2003) (refusing to order production of highly sensitive, commercial information despite presence of protective order).

Similarly, when analyzing the risk of disclosure to experts (as would also be the case here), several courts have noted the difficulty they would face in “compartmentalizing” from other information the highly confidential, information that would be obtained. The same experts – and attorneys – appear and reappear in these cases involving similar disputes between brand and generic pharmaceutical companies. *See Litton Indus., Inc. v. Chesapeake & Ohio Ry. Co.*, 128 F.R.D. 528, 531 (E.D. Wisc. 1990) (“[T]his court is not sanguine that a protective order could be constructed to sufficiently maintain the highly sensitive, nature of this information. [O]nce an expert has digested this highly confidential it is unlikely that the expert will forget. ... If the expert is called upon two years after this litigation to assist a potential competitor ... will he really be able to compartmentalize all he or she has learned and not use any of the information obtained ...?); *Greater Rockford Energy & Tech. Corp. v. Shell Oil Co.*, 138 F.R.D. 530, 538 (C.D. Ill. 1991) (denying certain requests for highly sensitive information, even though “Highly Confidential,” protective order was in place). The same concept applies to any recipient of highly sensitive information, expert or otherwise. One court has put the concept more bluntly; once knowledge has been gained, people cannot “perform a prefrontal lobotomy” on themselves. *Fleming Sales Co. v. Bailey*, 611 F. Supp. 507, 514 (N.D. Ill. 1985) (*quoted in Autotech Techs. Ltd. P’ship v. Automationdirect.com, Inc.*, 237 F.R.D. 405, 408 (N.D. Ill. 2006)).

As this Court found in its October ruling, where the relevance of the information is small, or non-existent, and the commercial harm is significant, as is the case here, a protective order covering documents produced to opposing parties is insufficient protection.

CONCLUSION

For the foregoing reasons, Lupin respectfully requests this Court to issue a Protective Order precluding plaintiffs from obtaining Lupin's highly sensitive commercial information concerning: (a) the pricing of Lupin's ANDA Product, (b) the identity of Lupin's customers and those customers' purchasing decisions, (c) the terms of Lupin's contracts with its customers, (d) the details of Lupin's sales to specific customers and sales channels, (e) profitability of Lupin's ANDA Product, (f) Lupin's marketing strategy, and (g) documents concerning settlement negotiations relating to transfer of the ANDA.

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